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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/472,691	12/27/1999	TERRY HERMISTON	ONYX1022	9088

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EXAMINER

SORBELLO, ELEANOR

ART UNIT PAPER NUMBER

1633

DATE MAILED: 12/03/2001

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/472,691

Applicant(s)

HERMISTON ET AL.

Examiner

Eleanor Sorbello

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09/10/01.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to amendment

1. Applicant's amendments and response to the official Office Action mailed 02/01/2001 as Paper No. 10, and Notice of Non-Compliant Amendment, mailed 08/01/01 has been received and filed on 08/08/01 and 09/20/01 as Paper Nos. 13 and 14 respectively. Claims 2, 6, 7, 10, 15 have been amended, and claim 15 has been added. **Claims 1-15 are pending.** Applicant's amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's argument.
2. Applicant's arguments are addressed below on a per section basis.
3. Applicants attention is drawn to Appendix A (page 4 of Response dated 9/10/01) that has misnumbered claims. Claims 3, 8, 9, 11 have been renumbered 2, 6, 7, 10.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 10, 11 remain rejected as stated in Office Action dated 2/1/01 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1633

Applicants claims are directed to methods of treatment of any neoplastic condition, by the administration of adenoviral vectors comprising any heterologous gene as the claims depend from claim 1.

Applicants have stated in Response page 3, paragraph 3 that they have performed experiments in vivo wherein MDA-MB-231 breast carcinoma xenografts in a nude mouse were injected with the virus of the instant invention wherein the heterologous gene was CD. Examiner wishes to point out that the nude mouse does not have an active immune system and therefore will not reject the virus as a normal mouse will, and therefore not be an appropriate animal model for these studies. Additionally, applicants claim a method of treating any neoplastic condition, but in applicants experiments they only performed direct tumor injection and broadly claim any neoplastic condition. Also applicants broadest claim encompasses the use of any heterologous gene for the treatment of any cancer which as stated in Office action dated 2/1/01 page 4, paragraph 2, certainly would not be expected to work.

Therefore, in view of the breadth of the claims, lack of guidance in the specification, nature of the invention one of skill in the art will require undue experimentation to use the invention as claimed.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1633

7. Claims 1-4 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the phrase “essentially exhibits”. This was rejected as being indefinite. However, applicant’s argued that the term ‘essentially’ was held acceptable in a fact profile similar to that presented by applicants and cite *In re Marosi* 218 USPQ 289, and request that the rejection be withdrawn. In this case, The US Court of Appeals Federal Circuit, overturned the Boards decision regarding the rejection based on the claim limitation “essentially free of alkali metal”, in the light of the specification and that known about the purity of the invention and the ability not to have an alkali metal in the finished product. However, examiner maintains that in the instant invention, applicants claim “a heterologous gene essentially exhibiting the temporal expression pattern seen in the deleted E1B genes” that were deleted, is inserted in place of the deleted E1B region. However, the specification does not teach one of skill how one is to accomplish this, and no where in the specification is there a definition of the phrase “essentially exhibits”. The metes and bounds of this phrase is unclear. The specification (on page 4, lines 2-4) merely states that the heterologous gene has a similar temporal expression pattern to the endogenous gene it replaces. Therefore, claim 1 and claims that depend therefrom remain rejected for reasons of record.

Art Unit: 1633

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

9. Examiner notes that a typographical error was made in the Office Action dated 2/1/01 wherein the claims rejected under 35 USC 102, were made under the 102(b) statute rather than the 102(e) statute. The typographical error has been corrected below, and the rejection maintained.

10. Claims 1-3, 5-10, 12-15 are rejected under 35 USC § 102(e), as being anticipated by Bischoff, J. et al. (U.S. Pat. No: 6,080,578).

Applicant's arguments have been fully considered but they are not persuasive.

Applicants argue that Bischoff does not teach that vectors with E1B deletions are to be used for the treatment of cancer. However examiner disagrees because Bischoff's invention is directed to cytopathic adenoviral E1B mutated viruses for therapy and prophylaxis of neoplasia.

For the purpose of examination under 35 U.S.C. 102(e), these claims are being examined for features comprising the vector. The functional language of the claims do not lend any additional features to the vector.

The base claim is directed to a recombinant adenoviral vector comprising a deletion in the gene(s) of the E1B region, but which retains the E1B promoter, wherein a heterologous gene is substituted into the E1B region. The functional language of the claim is not been considered because the language of the claim implies that if the E1B region is deleted and substituted for by any heterologous gene, then the recombinant vector should exhibit the temporal expression pattern of the deleted E1B region.

Applicants argue on page 5, of Response dated August 1, 2001, that Bischoff did not teach E1B deletions wherein a heterologous gene was inserted which was operably linked to the E1B promoter. However, examiner directs applicants to col. 4, lines 42-52. Bischoff does teach a deletion in the E1B region, wherein a negative selectable gene is inserted such as HSVtk, which is operably linked to an early region E1B enhancer/promoter.

The aforementioned claims therefore are rejected for the reasons discussed above.

Conclusion

11. Claims 1-15 are rejected.
12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

Art Unit: 1633

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication should be directed to Eleanor Sorbello, who can be reached at (703)-308-6043. The examiner can normally be reached on Mondays-Fridays from 6.30 a.m. to 3.00 p.m. EST.

Questions of formal matters can be directed to the patent analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark, can be reached on (703) 305-4051. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

If the claims are amended canceled and/or added the applicants are required to follow Amendment Practice under 37 CFR § 1.121 (<http://www.uspto.gov>) and A CLEAN COPY OF ALL PENDING CLAIMS IS REQUESTED to facilitate further examination.

**SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER**